

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/68553

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **A61B 17/00**(2006.01)
A61F 5/00(2006.01)

USPC: 604/500,606/86R

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/500; 606/86R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

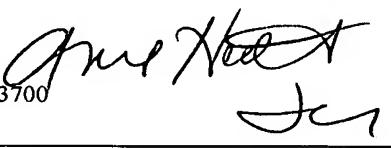
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST search terms: spinal, stenosis, epidural, tissue

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|------------------------------------------------------------------------------------|-----------------------|
| X | USPN 6,010,493 (SNOKE) 4 January 2000 (04.01.2000) | 1 |
| --- | | ----- |
| Y | | 2-19 |

Further documents are listed in the continuation of Box C. See patent family annex.

| | |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| * Special categories of cited documents: | |
| "A" | document defining the general state of the art which is not considered to be of particular relevance |
| "E" | earlier application or patent published on or after the international filing date |
| "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) |
| "O" | document referring to an oral disclosure, use, exhibition or other means |
| "P" | document published prior to the international filing date but later than the priority date claimed |
| "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "&" | document member of the same patent family |

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of the actual completion of the international search 02 September 2008 (02.09.2008) | Date of mailing of the international search report 11 SEP 2008 |
| Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 272-3201 | Authorized officer Nicholas Lucchesi Telephone No. (571) 272-3700  |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
DAVID A. ROSE
CONLEY ROSE, P.C.
P.O. BOX 3267
HOUSTON, TX 77253-3267

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

| | |
|-------------------------------------|-------------|
| Date of mailing (day/month/year) | 11 SEP 2008 |
|-------------------------------------|-------------|

| | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------|--|
| Applicant's or agent's file reference 2329-01101 | | FOR FURTHER ACTION See paragraph 2 below | |
| International application No. PCT/US07/68553 | International filing date (day/month/year) 09 May 2007 (09.05.2007) | Priority date (day/month/year) 09 May 2006 (09.05.2006) | |
| International Patent Classification (IPC) or both national classification and IPC IPC: A61B 17/00(2006.01) A61F 5/00(2006.01) USPC: 604/500,606/86R | | | |
| Applicant X-STEN, CORP. | | | |

1. This opinion contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------------------------------------|
| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 02 September 2008 (02.09.2008) | Authorized officer Nicholas Lucchesi Telephone No. (571) 272-3700 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------------------------------------|

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US07/68553

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

the international application in the language in which it was filed

a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

a sequence listing

table(s) related to the sequence listing

b. format of material

on paper

in electronic form

c. time of filing/furnishing

contained in the international application as filed.

filed together with the international application in electronic form.

furnished subsequently to this Authority for the purposes of search.

4. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/US07/68553

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>2-19</u> | YES |
| | Claims <u>1</u> | NO |
| Inventive step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-19</u> | NO |
| Industrial applicability (IA) | Claims <u>1-19</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by USPN 6,010,493 to Snone.

Claims 2-19 lack an inventive step under PCT Article 33(3) as being obvious over Snone.

With respect to independent claim 1, Snone discloses a method for treating stenosis in a spine of a patient having a median plane, the spine including a spinal canal having a posterior surface, a dural sac and an epidural space between the posterior surface and dural sac, the location of the stenosis determining a region of interest in the spine (abstract), comprising the steps of: a) generating at least one view of a portion of the spinal canal in the region of interest (163); b) compressing the dural sac in the region of interest by injecting a fluid to form a safety zone and establish a working zone in the region of interest, the safety zone lying between the working zone and the dural sac (166); c) percutaneously accessing the epidural space in the region of interest on a first lateral side of the median plane; d) inserting a tissue removal tool into tissue in the working zone on the first lateral side of the median plane (165); e) using the tissue removal tool to percutaneously reduce the stenosis on the first lateral side of the median plane (171); and f) utilizing the at least one view to position the tissue removal tool during at least a part of step d) and at least part of step e) (figures 13 and 14).

Dependent claims 2-19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.